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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,258	09/25/2003	Robert O. Williams	10071-037-999	3229

20582 7590 07/14/2008

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
07/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,258	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-58 are presented for examination.

Upon further consideration of the claimed subject matter, the restriction requirement of January 10, 2007 has been VACATED in lieu of the following requirement, which supersedes the previous requirement of January 10, 2007 and provides clarification on the species elections required for each invention.

Requirement for Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23, drawn to an emulsion or patch comprising an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant, classified in class 424, subclasses 401, 443 or 449, for example.

II. Claims 24-40 and 58, drawn to a method for treating pain comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant, classified in class 424, subclasses 401, 443 or 449, for example.

III. Claims 41-57, drawn to a method for inducing local anesthesia comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant, classified in class 424, subclasses 401, 443 or 449, for example.

The inventions are distinct, each from the other, for the following reasons:

Inventions I and Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the

instant case, the product as claimed can be used in a materially different process of using that product, namely, for treating fibromyalgia.

Inventions II and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

In particular, Inventions II and III are related because they recite the topical administration of an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant to a patient in need thereof. However, Invention II is directed to a method for treating pain, wherein the amount of the emulsion is effective to achieve such an objective. The method of Invention III is directed to a method for inducing local anesthesia, wherein the amount of the emulsion is effective to achieve such an objective. Accordingly, the processes of Inventions II and III clearly have different functions and/or effects. It is additionally noted that the treatment of pain does not necessarily result in the complete induction of local anesthesia at the site of application.

Further, Inventions II and III comprise steps that are not required for any other method. Invention II requires the application of the emulsion in an amount effective to treat pain. Invention III requires the application of the emulsion in an amount effective to induce local anesthesia. In other words, the amounts required to achieve each objective are distinct and unique to the desired objective.

Accordingly, the modes of operation, functions and/or effects of the methods are clearly distinct from one another, despite the fact that the Inventions are related solely on the basis of the topical application of an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant. In view of the fact that the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants, the inventions are properly held to be patentably distinct from one another.

Restriction for examination purposes as indicated is proper because all of the inventions listed *supra* are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 C.F.R. 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 C.F.R. 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable upon the elected invention.

Should Applicant traverse on the ground that the inventions are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of

the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of Species Requirement

This application contains claims directed to patentably distinct species of (i) antidepressant (claims 1-57), (ii) NMDA receptor antagonist (claims 1-57), (iii) lipophilic component (claims 1-57), (iv) surfactant (claims 1-57), (v) lipophilic intradermal penetration enhancer (claims 19-20, 39-40 and 56-57) (vi) humectant (claims 21and 58) and (vii) anti-foaming agent (claims 21 and 58).

Election of species should be made consistent with the following instructions:

(A) Should Applicant elect the Invention of Group I, Applicant is required to make the following elections:

(1) Election of a **single disclosed specie** of antidepressant selected from those specifically claimed (see, e.g., claims 4-8) **or** an antidepressant from those specifically disclosed in the instant specification.

(2) Election of a **single disclosed specie** of NMDA receptor antagonist from those specifically claimed (see, e.g., claims 12-13) **or** a NMDA receptor antagonist from those specifically disclosed in the instant specification.

(3) Election of a **single disclosed specie** of lipophilic component from those specifically claimed (see, e.g., claims 16-18) **or** a lipophilic component from those specifically disclosed in the instant specification.

(4) Election of a **single disclosed specie** of surfactant from those specifically disclosed at p.18, l.20-p.19, l.23 of the instant specification.

(5) Election of whether a lipophilic intradermal penetration enhancer (i) **IS NOT** or (ii) **IS** present in the emulsion.

Should Applicant elect that a lipophilic intradermal penetration enhancer **IS** present in the emulsion, Applicant is further required to elect a **single disclosed specie** of lipophilic intradermal penetration enhancer from those specifically claimed (see, e.g., claim 20) **or** a lipophilic intradermal penetration enhancer from those specifically disclosed in the instant specification.

(6) Election of whether a humectant **OR** an anti-foaming agent (iii) **IS NOT** or (iv) **IS** present in the emulsion (as provided for in instant claim 21). **Note that the instant claims provide only for the use of a humectant OR an anti-foaming agent, not both together**. Accordingly, an election of both a humectant AND an anti-foaming agent will be held non-responsive.

Should Applicant elect that a humectant **IS** present in the emulsion, Applicant is further required to elect a **single disclosed specie** of humectant from those specifically disclosed at p.20, l.28-31 of the instant specification.

Should Applicant elect that an anti-foaming agent **IS** present in the emulsion, Applicant is further required to elect a **single disclosed specie** of anti-foaming agent from those specifically disclosed at p.20, l.19-20.

(B) Should Applicant elect the Invention of Group II, Applicant is required to make the following elections:

(7) Election of a **single disclosed specie** of antidepressant selected from those specifically claimed (see, e.g., claims 27-31) **or** an antidepressant from those specifically disclosed in the instant specification.

(8) Election of a **single disclosed specie** of NMDA receptor antagonist from those specifically claimed (see, e.g., claims 35-36) **or** a NMDA receptor antagonist from those specifically disclosed in the instant specification.

(9) Election of a **single disclosed specie** of lipophilic component from those specifically disclosed in the instant specification.

(10) Election of a **single disclosed specie** of surfactant from those specifically disclosed at p.18, l.20-p.19, l.23 of the instant specification.

(11) Election of whether a lipophilic intradermal penetration enhancer (i) **IS NOT** or (ii) **IS** present in the emulsion.

> Should Applicant elect that a lipophilic intradermal penetration enhancer **IS** present in the emulsion, Applicant is further required to elect a **single disclosed specie** of lipophilic intradermal penetration enhancer from those specifically claimed (see, e.g., claims 39-40) **or** a lipophilic intradermal penetration enhancer from those specifically disclosed in the instant specification.

(12) Election of whether a humectant **OR** an anti-foaming agent (iii) **IS NOT** or (iv) **IS** present in the emulsion (as provided for in instant claim 58). **Note that the instant claims provide only for the use of a humectant OR an anti-foaming agent, not both together**. Accordingly, an election of both a humectant AND an anti-foaming agent will be held non-responsive.

> Should Applicant elect that a humectant **IS** present in the emulsion, Applicant is further required to elect a **single disclosed specie** of humectant from those specifically disclosed at p.20, l.28-31 of the instant specification.
>
> Should Applicant elect that an anti-foaming agent **IS** present in the emulsion, Applicant is further required to elect a **single disclosed specie** of anti-foaming agent from those specifically disclosed at p.20, l.19-20.

(C) Should Applicant elect the Invention of Group III, Applicant is required to make the following elections:

(13) Election of a **single disclosed specie** of antidepressant selected from those specifically claimed (see, e.g., claims 44-48) **or** an antidepressant from those specifically disclosed in the instant specification.

(14) Election of a **single disclosed specie** of NMDA receptor antagonist from those specifically claimed (see, e.g., claims 52-53) **or** a NMDA receptor antagonist from those specifically disclosed in the instant specification.

(15) Election of a **single disclosed specie** of lipophilic component from those specifically disclosed in the instant specification.

(16) Election of a **single disclosed specie** of surfactant from those specifically disclosed at p.18, l.20-p.19, l.23 of the instant specification.

(17) Election of whether a lipophilic intradermal penetration enhancer (i) **IS NOT** or (ii) **IS** present in the emulsion.

> Should Applicant elect that a lipophilic intradermal penetration enhancer **IS** present in the emulsion, Applicant is further required to elect a **single disclosed specie** of lipophilic intradermal penetration enhancer from those specifically claimed (see, e.g., claims 56-57) **or** a lipophilic intradermal penetration enhancer from those specifically disclosed in the instant specification.

Applicant is cautioned that the election of a particular specie of antidepressant, NMDA receptor antagonist, lipophilic component, surfactant, and, if applicable, a lipophilic intradermal penetration enhancer, humectant, or anti-foaming agent, wherein the elected specie(s) is/are not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

Currently, claims 1-58 are generic.

The species are independent or distinct because the species of antidepressants, NMDA receptor antagonists, lipophilic components and surfactants recited in the present claims are structurally and/or chemically distinct from any one other of the respective components encompassed by the present claims such that a comprehensive search of the patent and non-patent literature for, for example, any one such antidepressant would not necessarily result in a comprehensive search of any one or more or all of the other antidepressants encompassed by the claims. Similar reasoning applies equally to the chemically and structurally distinct NMDA receptor antagonists, lipophilic components and surfactants encompassed by the present claims, but for the obvious difference in the type of compound. It remains that, though Applicant has discovered that this generic combination of agents is amenable for use in treating pain or inducing local anesthesia, the art may have recognized a different advantage or benefit to any one or more of these combination(s) of compounds that differs from the advantage that Applicant has discovered and, thus, the search for any one combination would not necessarily encompass a comprehensive search for any one other combination presently claimed. Furthermore, the disparate nature and variability encompassed by these broad genera of compounds precludes a quality examination on the merits not only because a burdensome search would be required for the entire scope of the claim(s), but also because consideration of the findings of such a search for compliance with the statutes and requirements set forth under 35 U.S.C. 101, 102, 103 and 112 would be unduly burdensome.

Also, the species are independent or distinct because claims to the different species of compounds recite the mutually exclusive characteristics of such species. In addition, these species are not necessarily obvious variants of each other based on the current record and there is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to

another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that a reply to this requirement must include an identification of the single disclosed species of antidepressant, NMDA receptor antagonist, lipophilic component, surfactant, and, if applicable, a lipophilic intradermal penetration enhancer, humectant, or anti-foaming agent, that is elected consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 C.F.R. 1.144.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

July 9, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614